## 1.5 Create AE

### Description
This use case identifies the process whereby actors with the appropriate role authority will create a new AE Entry for a given Study Participant linked to an existing protocol.

### Actors
The PI or any other designated user of *AERS* [sm] with appropriate role authority for this function.

### Pre-Conditions
The actor has successfully logged into the system. The protocol has successfully been created. The Study Participant exists and has successfully been linked to an existing protocol.

### Basic Course
1. The actor searches and selects a patient on which to record an AE.
2. The actor selects option to create a new AE Entry.
3. The initial data screen is presented with protocol and Study Participant identified.
4. Actor prompted to identify AE:
   - Pick list items of titles (e.g if protocol is CTCAE driven then use Categories and AE titles) or MedDRA code
   - AE Start/Known Date (See data table and dictionary for definition)
5. *AERS* [sm] searches for possible duplicate of existing AEs (See Notes business rule 5 below). No duplicate found **(^Alternate course 1.5.5 Possible Duplicate AE for Study Participant Found)**
6. Actor selects 'SAVE' button.
7. *AERS* [sm] creates unique AE Entry ID.
8. Actor is viewing a confirmation window and can choose to 'EXIT' (defaults to main menu. See Note 6 below) or 'CONTINUE DATA COLLECTION' **(see Use Case 1.6)**.

### Post Conditions
After successful completion of this use case, the actor will have created an AE for a Study Participant linked to an existing Protocol.

### Alternate Course 1.5.5 Possible Duplicate AE for Study Participant Found
1. AERS searches for possible duplicate. Matches on data element indicated below and in business rule.
2. Notifies the actor of duplicate and displays the possible duplicate(s).
3. Actor is prompted to 'CONTINUE' the create AE function - then continues at Basic Course step 7
   **or** 'CANCEL' create AE function – then defaults to the main menu.

### Extension Points
*AERS* [sm] AE Entry detail validation fails. (Detail course pending)
Actor saves and chooses to complete AE Entry at a later time.

**Data Item**

| Data Item | Type | Notes/Validation Rules |
|---|---|---|
| AE Start Date | Required for duplicate check & sponsor reports | Def: date recorded in source documentation or by Pt. or family caregiver. |
| | | |
| | | |
| MedDRA Code | Required if AE category and title not provided. For duplicate check and Reg Agency Reporting | (*Issue other non-MedDRA AE codes used by CTC; consider "concepts"; use MedDRA when needed for reporting) |
| CTC AE Category | Required if MedDRA Code not provided. For duplicate check and Reg Agency Reporting | |
| AE Title | Requried if MedDRA Code not provided. For duplicate check and Reg Agency Reporting | |
| | | *Issue: Consider AE Reference IDs as assigned by system-internal; also visible reference ID from external agency-Mod4 |

**Notes**

1. Pre-existing conditions system derived from previous AE records
2. Dose Limiting toxicity derived protocol trigger; dose limiting management not covered in initial
3. Reportable function derived from protocol trigger
4. Note issue for other non-MedDRA code used by CTC
5. Business rule for determining a duplicate AE: a) match on MedDRA Code and if start date is >= to that of an existing AE
   b) or if start date falls within date range (start and stop dates) of existing AE (*Issue continue to work this-add consideration of "Other: specify")
6. If the actor chooses to 'EXIT' on basic Course step 9 then AERS will notify the user to complete the data collection within X?X time frame.
   (*Issue for escalation procedure based on grade and/or reporting needs Do we need to add grade as a required field now or ask is this serious ye/no then escalate based on answer?)

**Risks**

Pending.

**Use Case dependency**

13.0 User login
1.1 Create Protocol Data for AE Abstraction
1.2 Create and Link Study Participant to Protocol

**Priority Assignment:** TBD

1 – critical to prototype; 2 – future development; 3 – out of grant scope

## 1.6 AE Data Collection

### Description
This use case identifies the process whereby actors with the appropriate role authority can enter data on an existing AE for an existing Study Participant linked to an existing protocol.

### Actors
Any user designated user of *AERS* sm with appropriate role authority.

### Pre-Conditions
The actor has logged into *AERS* sm and has the appropriate role authority to access this function. An AE exists for an existing Study participant. The protocol has successfully been created. The Study Participant has successfully been linked to an existing protocol.

### Basic Course
1. The actor selects option to search for AE Entries by Study Participant or Protocol.
2. *AERS* sm presents a list of AEs for editing.
3. Actor selects the interested AE.
4. AERS displays the AE data entry screen with current data.
5. Actor completes data entry. (* Issue SIG exercise – Sequence the data entry and expand on business rules. e.g.AdEERs reporting rules )
   - AE Grade
   - Expectedness
   - Attribution
   - Intervention (e.g. Chemotherapy – then will be prompted to enter Course #/Cycle # during AE Use Case 1.6 data collection)
   - Study Relatedness
   - Action Outcome
   - AE Stop Date
6. Actor selects to save edits
7. *AERS* sm validates data detail and displays verification message.
8. *AERS* sm records timestamp and user id on successful update; audit file logged.

### Post Conditions
After successful completion of this use case, the actor will have saved edits to an existing AE for a Study Participant linked to an existing protocol. Time stamp of last saved edits with User ID are readily viewable. An audit log of updates is available. Reporting Triggers may have been invoked.

### Alternate Course
Pending.

### Extension Points
Based on invoked triggers (pending)

### Data Item

| Data Item | Type | Notes/Validation Rules |
|---|---|---|
| CTC Grade | Required | Coded 0-5 |
| Expectedness | Required | Yes./ No |
| Attribution | Required | Coded 0-5 |
| AE Stop Date | Not Required | (*Issue notify for AE that is started by not stopped) |
| Intervention | Not required | Chemotherapy<br>Drug Intervention (Non-Chemotherapy)<br>Surgery<br>Radiation Therapy<br>RadioImmunology<br>Transplant |
| Course #/ Cycle # | Required if Intervention = Chemotherapy | (*Issue: Other data r/t to course and cycle TBD) |
| Study Relatedness | TBD by SIG | Elements TBD ( Attribution?) from Web board. |
| Action | TBD by SIG | Elements TBD from Web board. |
| Outcome | TBD by SIG | Elements TBD from Web board. |

**Notes**

None identified at this time.

**Risks**

Pending

**Use Case dependency**

13.0 User login
1.1 Create Protocol Data for AE Abstraction
1.2 Create and Link Study Participant to Protocol
1.5 Create AE

**Priority Assignment: TBD**

1 – critical to prototype; 2 – future development; 3 – out of grant scope